WHAT IS CLAIMED IS:

1. A test kit for detecting bacterial endotoxin in an aqueous solution using a gel-clot method, said test kit comprising:
   (a) at least one first container containing freeze dried, endotoxin-specific, horseshoe crab amebocyte lysate, whereby the sensitivity of the lysate is pre-certified;
   (b) at least one second container containing a defined quantity of endotoxin to serve as a positive control, wherein said defined quantity of endotoxin is pre-certified to positively react with the amebocyte lysate present in said first container; and
   (c) at least one disposable endotoxin-free transfer instrument.
2. The test kit of claim 1, wherein said horseshoe crab amebocyte lysate in component (a) is from *Limulus polyphemus*.
3. The test kit of claim 2, wherein said defined quantity of endotoxin in component (b) is two times the sensitivity of the amebocyte lysate in component (a).
4. The test kit of claim 3, wherein the level of sensitivity of the test kit for detecting endotoxin can vary based on the formulation of the amebocyte lysate in container one and the incubation time of containers one and two.
5. The test kit of claim 2, wherein the amount of said amebocyte lysate is 0.4, 0.5, or 0.6 mL.
6. The test kit of claim 5, wherein the amount of said amebocyte lysate is 0.5 mL.
7. The test kit of claim 2, wherein said aqueous solution is purified, distilled, sterile, non-sterile, or filtered water, water for injection, water for irrigation, or reverse osmosis water.
8. The test kit of claim 2, wherein said aqueous solution is dialysate.
9. The test kit of claim 2, wherein said first and second containers are test tubes.

10. The test kit of claim 9, wherein said test tubes are 12 x 75 mm and round-bottomed.

11. The test kit of claim 2, where said disposable endotoxin-free transfer instrument is a pipette.

12. The test kit of claim 2, further comprising written instructions for carrying out the test.

13. The test kit of claims 2, 3, 4, or 11, further comprising a written certificate of analysis of the amebocyte lysate sensitivity, the quantity of endotoxin in the positive control, and/or the endotoxin-free nature of the transfer instrument.

14. In a method for specifically detecting bacterial endotoxin in an aqueous solution by a gel clot method using horseshoe crab amebocyte lysate, the improvement comprising using a defined quantity of endotoxin to serve as a positive control, wherein said defined quantity of endotoxin is pre-certified to positively react with the horseshoe crab amebocyte lysate, and whereby the sensitivity of said gel clot method can vary based on the time of incubation of the test.

15. The method of claim 14, wherein said horseshoe crab amebocyte lysate is from *Limulus polyphemus*.

16. The method of claim 15, wherein the sensitivity of said gel clot method can vary based on the formulation of the amebocyte lysate.